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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/361,542 07/27/99 DOBROZSI

D 7247M

EXAMINER

HM12/0111

PULLIAM, A

ART UNIT	PAPER NUMBER
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1615

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01/11/01

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No.	Applicant(s)
	09/361,542	DOBROZSI, DOUGLAS JOSEPH
	Examiner	Art Unit
	Amy E Pulliam	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 December 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12, 24, 26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12, 24, 26 and 28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	20) <input type="checkbox"/> Other: _____

DETAILED ACTION

Receipt is acknowledged of the Amendment A, received December 1, 2000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 24, 26, and 28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 733 357 to Boltri *et al.* (hereinafter Boltri). Boltri discloses a topical formulation which is nebulizable by a mechanical pump, and contains colloidal silica (abstract). Boltri further teaches that the pharmaceutical formulation of his invention comprises colloidal silica in an amount from 2 to 15%, and a pharmaceutically active ingredient, as well as water and any other excipients conventionally used in pharmaceutical techniques (p 2, l 22-26). Further, Boltri teaches that the average diameter of the silica particles is between 7 and 40 nm, which reads on applicant's claim to less than 1 micron. Boltri also teaches that the composition can be used for topical, vaginal, nasal, and otological administration (p 3, l 15-17).

This disclosure teaches the above claims, because these claims are drawn to a composition, and Boltri teaches the same components in the

composition. Further, because Boltri teaches the same components in the composition, the ratios and viscosities claimed by applicant are considered inherent to the composition, and absent any evidence to the contrary, these characteristics render no patentable weight to the instant application.

Boltri does not teach the specific inclusion of citric acid, however Boltri does teach the inclusion of pharmaceutical excipients in general, and it is the position of the examiner that one of ordinary skill in the art would use any well known excipient in the formulation disclosed by Boltri.

Further, Boltri does not disclose the method of coating the alimentary canal or treating the upper respiratory tract. However, based on the teachings that the formulation can be nebulized, it is the position of the examiner that one of ordinary skill in the art would take this to mean the composition could be inhaled through means well known in the pharmaceutical art. Therefore, one of ordinary skill in the art would have been motivated to use Boltri's formulation to treat the alimentary canal through inhalation therapy. One of ordinary skill in the art would expect the same results in this type of treatment as in treating the nasal and vaginal areas. Therefore, this invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found persuasive. Applicant argues that because he has cancelled the claims relating to nasal formulation, the reference no longer applies to the claimed invention. Applicant argues that Boltri *et al.* only teach topical, nasal, vaginal, and otological

formulations, whereas applicant is claiming an oral formulation. Applicant further argues that there is no motivation to modify the Boltri *et al.* invention to make it orally administratable. However, the reference teaches nasal administration, meaning the components of the composition are taken internally, and therefore have no detrimental effect. Therefore, nothing in the reference teaches away from administration of same claimed composition orally through a nebulizer instead of nasally. Further, as stated above, it is well known in the art that nebulized compositions can be administered orally or nasally.

Further, applicant argues that Boltri *et al.* do not teach the oral aqueous carrier as claimed by applicant. Lastly, applicant argues that the focus of his invention is a swallowable liquid, which is not taught by Boltri *et al.*. With regards to applicant's argument that the reference does not teach an oral aqueous carrier, the examiner disagrees and points out on page 2, line 24, Boltri *et al.* teach that water, and any other conventional excipients can be used. Water reads on applicant's claim to an oral aqueous carrier

Applicant has amended claim 1 to introduce the limitation "wherein the composition is administered by swallowing." However, this addition does not overcome the rejection because the claims are composition claims, and intended use has no patentable significance in composition claims. . .

Lastly, applicant argues that the Boltri *et al.* invention requires mechanical stress, which differentiates it from applicant's claimed invention. However, these limitations are not discussed in the claims, and therefore, based on applicant's

comprising language, do not distinguish applicant's claimed invention from the teachings of Boltri *et al.*.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding

is assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam
Patent Examiner
Art Unit 1615
January 9, 2001

THIRMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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T. K. Page